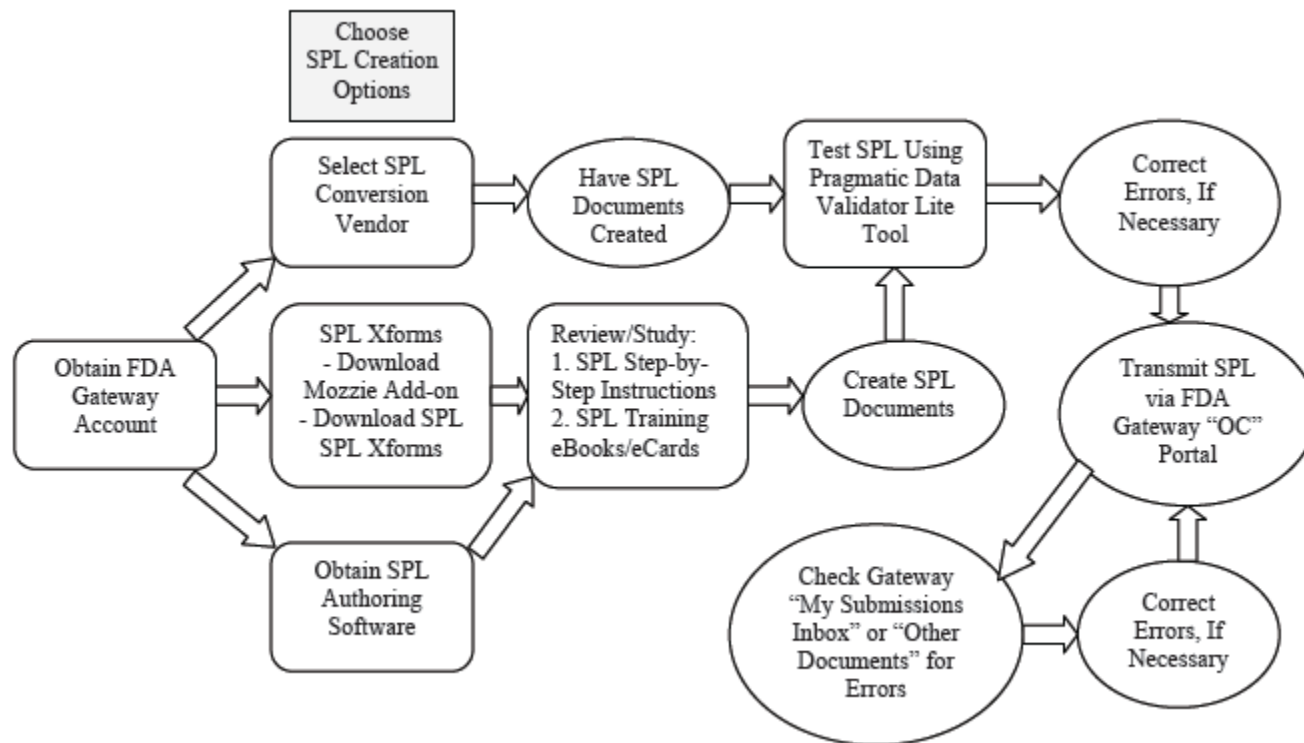


# Creating a Content of Labeling/ Drug Listing SPL Document - OTCs

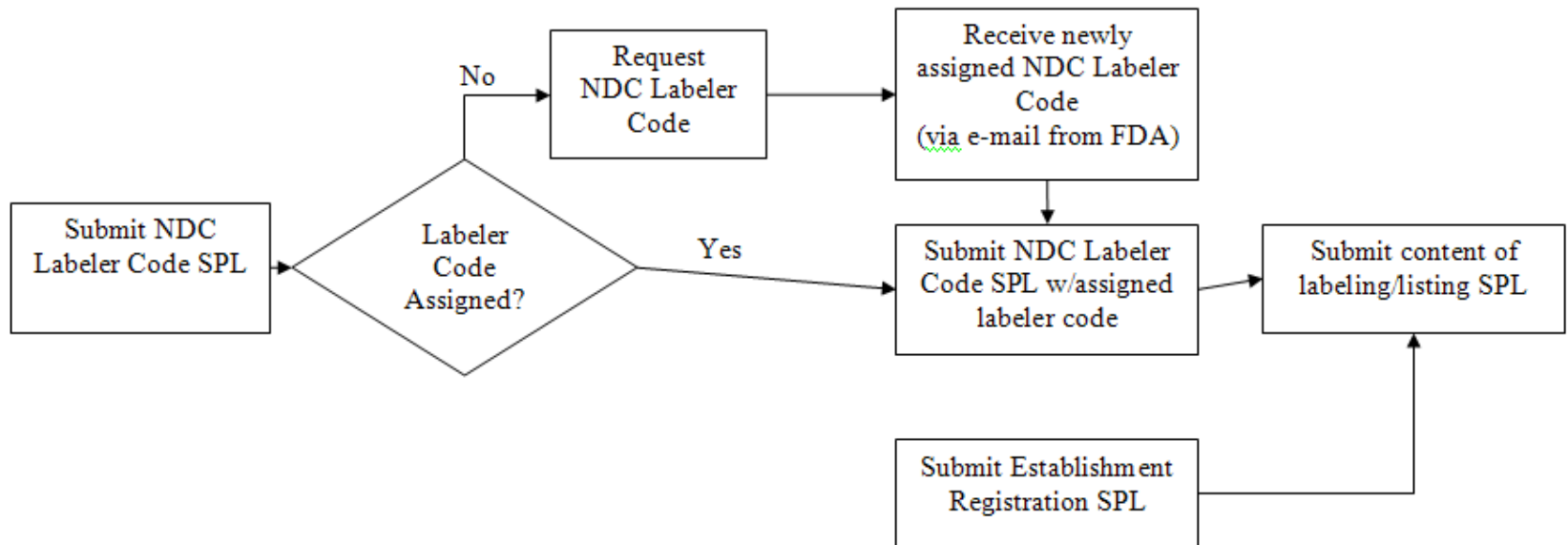
Lonnie Smith  
Policy Analyst  
FDA Data Standards Council



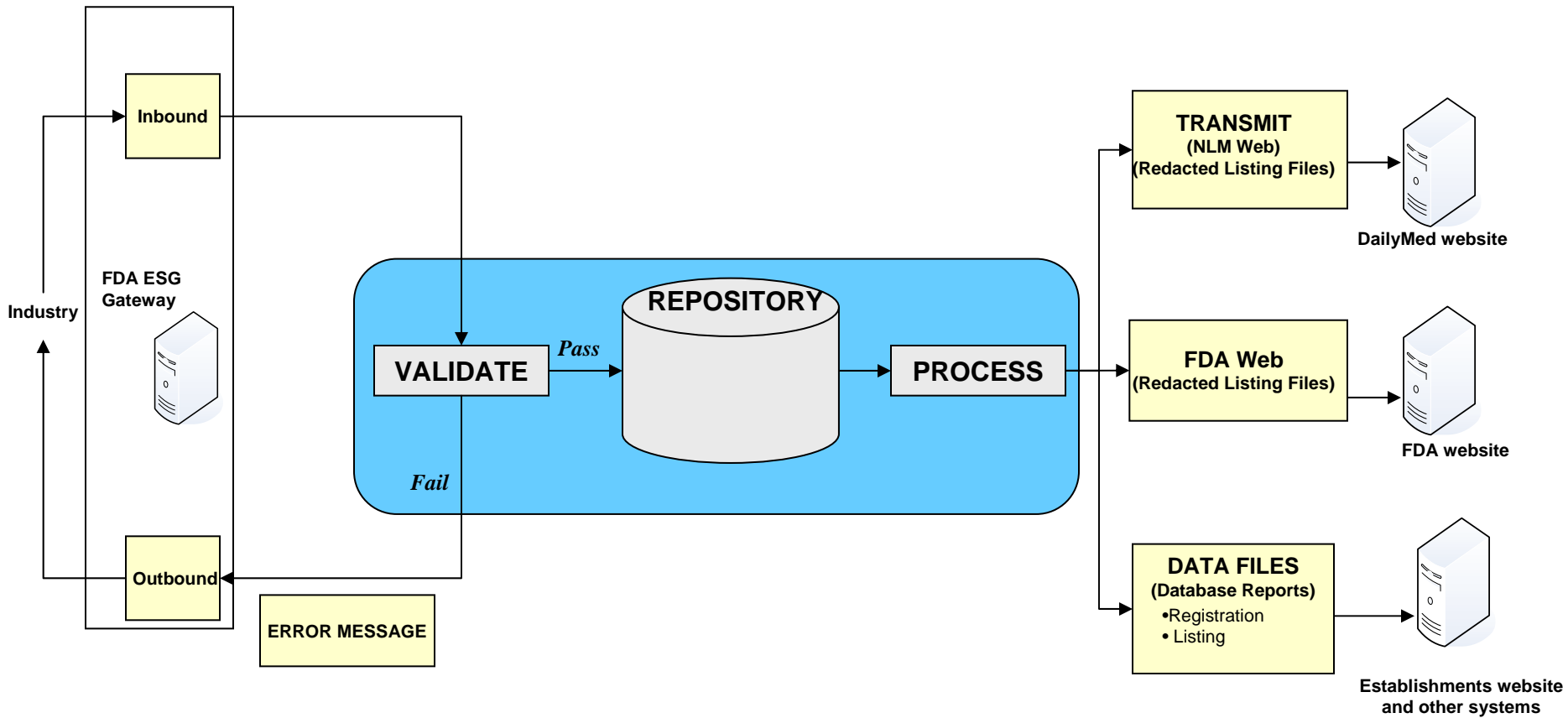
# “Road Map” Creation & Submission



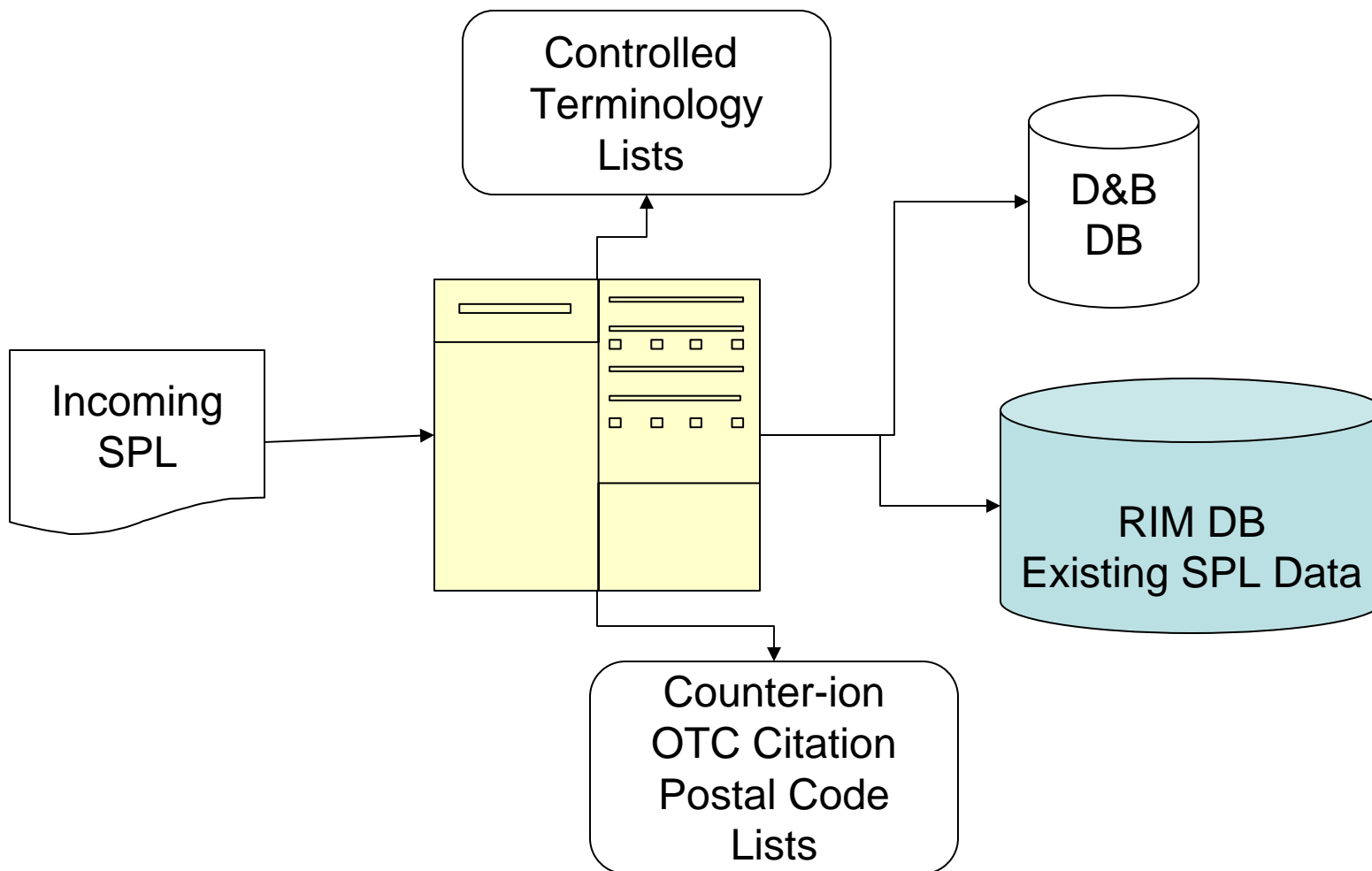
# SPL Submission Process



# eLIST



# Validation Model



# Validation Error Notifications

- Transmitted via FDA Gateway to submitter
- Transmissions occur within 36 hours (business days)
- In the form of a 2<sup>nd</sup> or 3<sup>rd</sup> acknowledgment
  - 2<sup>nd</sup> acknowledgment – system-generated message
  - 3<sup>rd</sup> acknowledgment – manually generated message with additional notes
- No 2<sup>nd</sup> or 3<sup>rd</sup> acknowledgment within 24 hours usually denotes that submission was accepted

# Technical Terms Glossary

Term	Definition
Core ID	A unique identifier which the FDA ESG assigns to every submission and uses for reference purposes
Document Root ID	Globally Unique Identifier (GUID) and is unique for each version of the document. Also referred as “root ID,” “ID,” “document ID,” or “document root ID.”
Effective Time	Provides a date reference to the SPL document version or a section including the year, month and day as yyyyymmdd.
GUID	Globally Unique Identifier (used as the SPL document root ID, setID, or section IDs)
SetID	Globally Unique Identifier (GUID) and is a unique identifier for the document that remains constant through all versions/revisions of the document.
UUID	Universal Unique Identifier (UUID) Synonymous w/GUID (see definition for GUID)
Version Number	Integer greater than zero that provides a sequence to the versions of the document.

# Components of OTC Drug Listing

- Drug Facts (content of labeling)
- Carton or container images
- Product Data Elements (drug listing)



# Drug Facts

- Sections of the drug facts label entered as text into the appropriate sections
- Select the appropriate section header (e.g. OTC Purpose (different than section title))
- Do not submit content of labeling text as an image (copy and paste text into appropriate fields)

# Drug Facts Example

## (snapshot of half of fictitious label)

PROPRIETARY NAME HERE SUFFIX HERE - active ingredient name here tablet  
Labeler name here

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

-----  
**Drug Facts**

**Active ingredient(s)**

Information required in 201.66(c)(2)

**Purpose**

Information required in 201.66(c)(3)

**Use(s)**

Information required in 201.66(c)(4)

**Warnings**

Applicable warning(s) in 201.66(c)(5)(i) and (ii)

**Do not use**

Information required in 201.66(c)(5)(iii)

# Carton/Container Images

- Representative sample of carton or container image
- Place image reference in the section **AFTER** the drug facts sections

# Carton/Container Image

## Inactive ingredients

Information required in 201.66(c)(8)

## Questions

Information specified in 201.66(c)(9)

## Principal Display Panel

OTC Medicine

Long Acting

Fast Relief

4 FL OZ (118 mL)



# Carton/Container Image cont...



# Product Data Elements

- Product
  - Product names
  - NDC Product Code
  - Source NDC Product Code (original manufacturer) – Repacked/Relabeled
- Description
  - Ingredients
  - Strength
  - Dosage form
  - Route of administration
  - Controlled substance code
  - Appearance
- How supplied
  - Packaged product

**Only terms in the controlled terminology are allowed.**

# Strength of Ingredient

- SPL R4 documents will allow companies to **designate strength based on the active ingredient, active moiety or a reference drug.**

## Example of non-solid dosage form

Numerator: **10 mg**

Denominator: **1 mL**

## Example of solid dosage form

Numerator: **10 mg**

Denominator: **None**

# Strength cont...

Product	Numerator unit	Denominator unit
Oral solid	Weight	Each
Oral liquid	Weight	Volume
Oral powder for reconstitution with a known volume	Weight	Volume
Oral powder for reconstitution with a variable volume	Weight	Each
Suppository	Weight	Each
Injection liquid	Weight	Volume
Injection powder for reconstitution with a known volume	Weight	Volume
Injection powder for reconstitution with a variable volume	Weight	Each
Inhaler powder	Weight	Each
Inhaler liquid	Volume	Each
Inhaler blister	Weight	Each
Topical cream or ointment	Weight	Weight
Topical gel or lotion	Weight	Volume
Transdermal patch	Weight	Time
Bulk liquid	Weight	Volume
Bulk solid	Weight	Weight



# Marketing Category

- Select the appropriate marketing category for the drug product.

Marketing Information	
Marketing Category	
NDA	

# Application or Citation Number

- Application numbers include the character application abbreviation and the numbers without spaces or dashes (e.g., NDA123456). Monograph citations include the number of the regulatory part (e.g., part234). (DO NOT enter “000000”)

	Application Number or Monograph Citation
	NDA000000

# Marketing Status & Date

- The marketing status describes the activity of the product
- SPL file is removed from the public repository. The expiration date of the last lot released to the marketplace provides an estimate of the date when the SPL file is removed.

# Marketing Status & Dates

- Status of product
  - **Active:** on the market
  - **Completed:** when marketing is done the drug is no longer going to be available on the market.
  - Active or completed timestamp: effectiveTime value.
- Low value
  - Time on the market
  - Determines release of CoL/Listing SPL to public
- High value
  - Time off the market (e.g. the expiration date of the last lot released to the market.)

Marketing Start Date	Marketing End Date
01/24/2005	

# Packaging

## Single level of packaging

PACKAGING			
#	NDC	Package Description	Multilevel Packaging
1	0009-3776-01	42.5 GRAM In 1 TUBE, WITH APPLICATOR	None

## Multi-level of packaging

PACKAGING			
#	NDC	Package Description	Multilevel Packaging
1	63481-445-01	1 VIAL In 1 BOX	contains a VIAL, MULTI-DOSE
1		10 MILLILITER In 1 VIAL, MULTI-DOSE	This package is contained within the BOX (63481-445-01)

# Marketing Status & Dates

- Status of product
  - **Active:** on the market
  - **Completed:** when marketing is done the drug is no longer going to be available on the market.
  - Active or completed timestamp: effectiveTime value.
- Low value
  - Time on the market
  - Determines release of CoL/Listing SPL to public
- High value
  - Time off the market (e.g. the expiration date of the last lot released to the market.)

Marketing Start Date	Marketing End Date
01/24/2005	

# Product Data Elements

PROPRIETARY NAME HERE SUFFIX HERE			
non proprietary name here tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0001-0001
Route of Administration	ORAL	DEA Schedule	
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
active ingredient name here (active moiety name here)	active ingredient name here	25 mg	
Inactive Ingredients			
Ingredient Name	Strength		
inactive ingredient name here			
Product Characteristics			
Color	blue (sky blue)	Score	2 pieces
Shape	OVAL (capsule-shaped)	Size	18mm
Flavor	BLUEBERRY	Imprint Code	
Contains			
Packaging			
#	Item Code	Package Description	Multilevel Packaging
1	NDC:0001-0001-50	50 TABLET ( TABLET) in 1 BOTTLE	None

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	citationhere	01/24/2005	

# Labeler/Establishment Data Elements

**Labeler** - Labeler name here (labeler DUNS Number here)

## Establishment

Name	Address	ID/FEI	Operations
Establishment name here		Establishment DUNS Number here	manufacture

## Establishment

Name	Address	ID/FEI	Operations
Establishment name 2 here		establishment DUNS Number here	manufacture

Revised: 02/2009

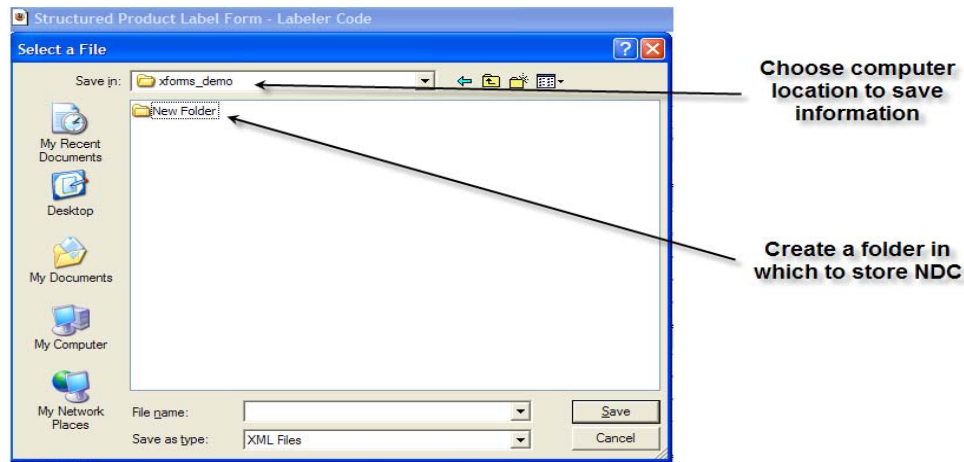
Labeler name here



# Updating SPL Document Tracking Information

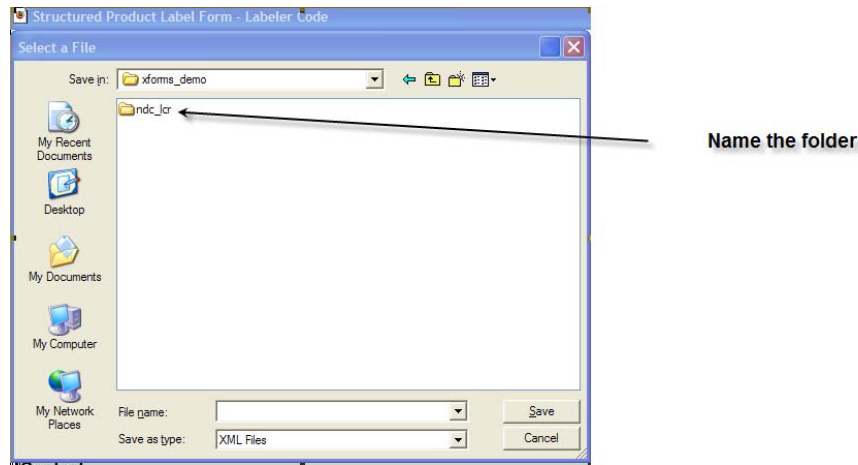
- **Use**
  - **new** id root
  - **new** version number
  - original setId
  - appropriate effective time
- **Misplaced SetID/SPL File**
  - E-mail core ID to [spl@fda.hhs.gov](mailto:spl@fda.hhs.gov)
  - Include contact person's name and DUNS Number which were included in original SPL file

# Creating the Submission Folder



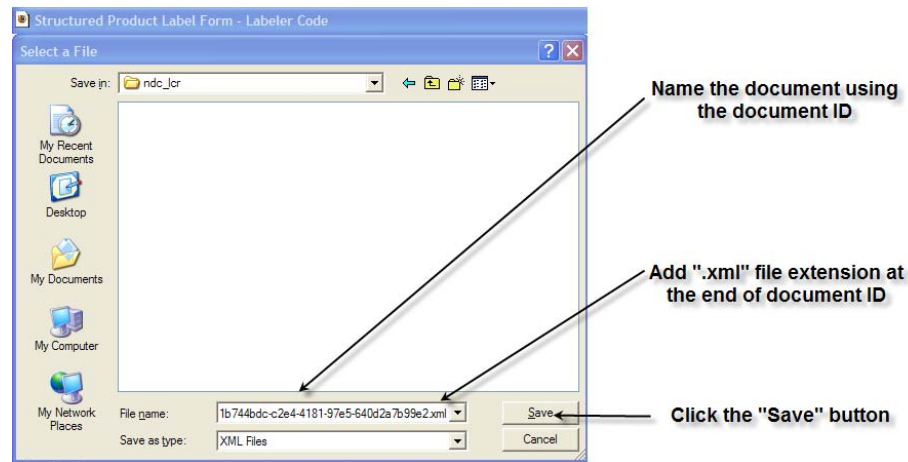
- Choose computer location in which to store folder to contain the SPL file.
- Create a folder in which to store the NDC Labeler Code SPL file.

# Naming the Submission Folder



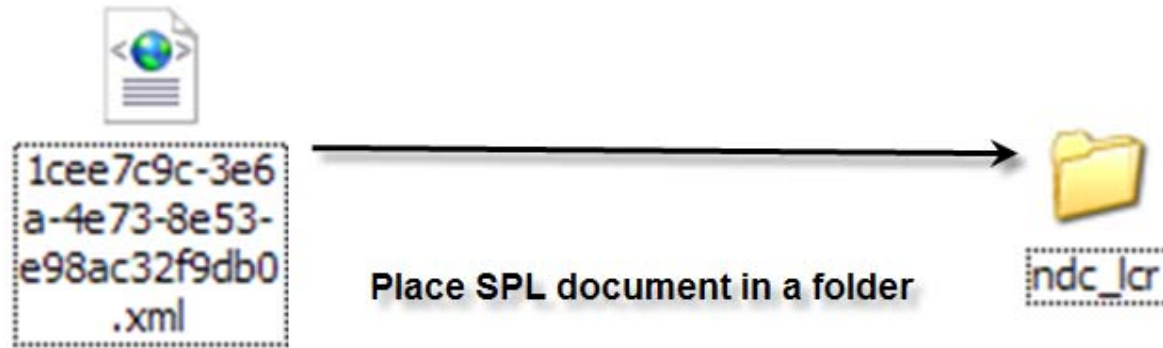
- There is no folder naming convention
- However, we recommend not using symbols in the name of the folder.

# Naming the SPL File



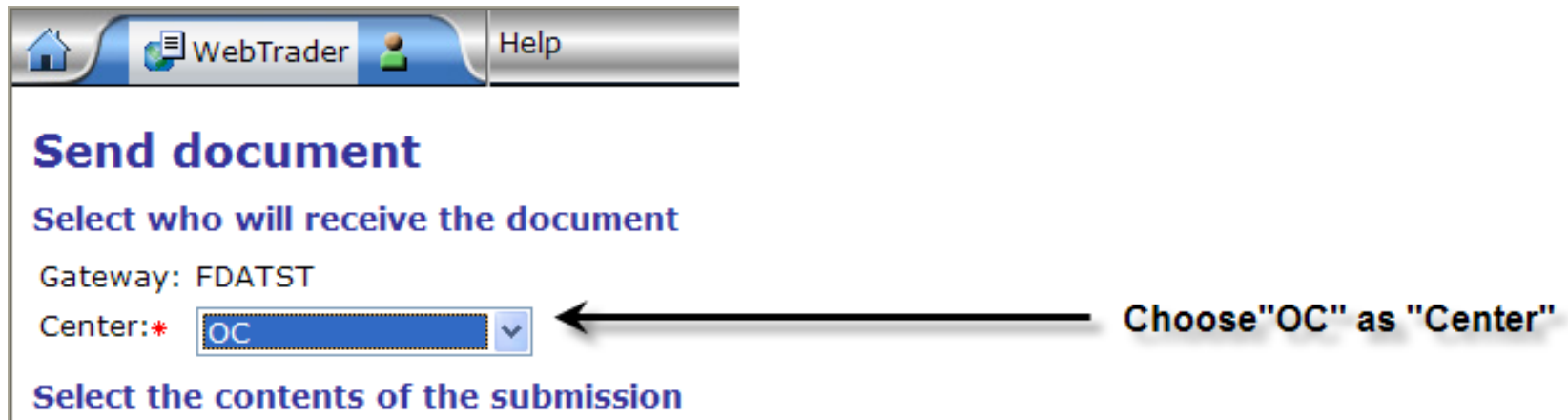
- Use the **document ID** (GUID) as the document file name
- Use “.xml” as the file extension
- Choose “Save” button
- If you do not follow these steps your SPL will **FAIL** validation.

# Place SPL File in Folder



- Place SPL document in a folder.
- Ensure that SPL file name is document root ID with “.xml” as file name extension.
- Only **ONE** SPL document per folder. If applicable, image files (jpeg) may accompany listing SPL document in folder.

# Choosing “Center”



WebTrader Help

**Send document**

Select who will receive the document

Gateway: FDATST

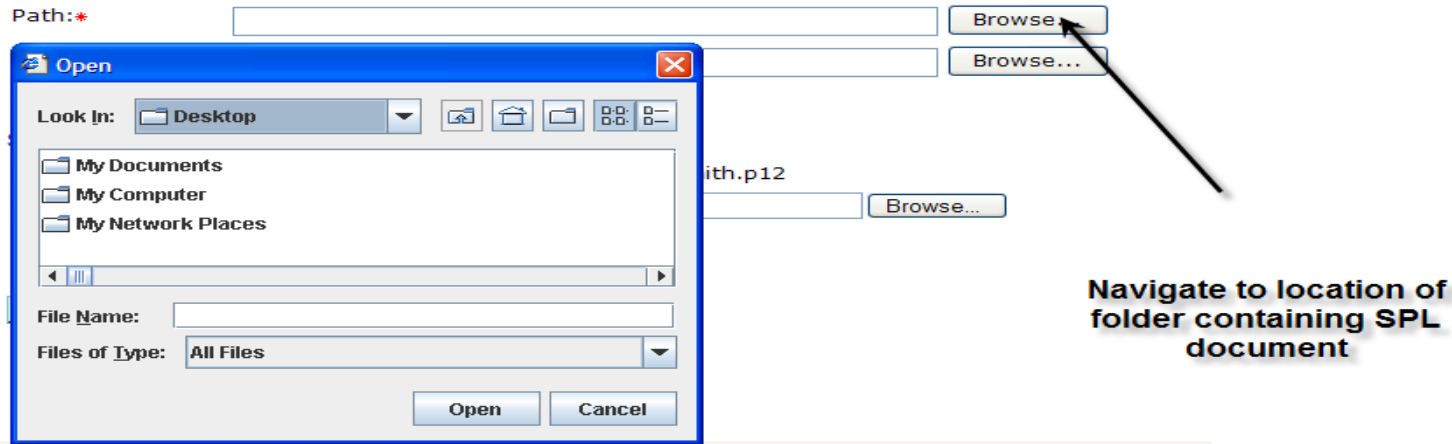
Center: \*  ▼

Select the contents of the submission

Choose "OC" as "Center"

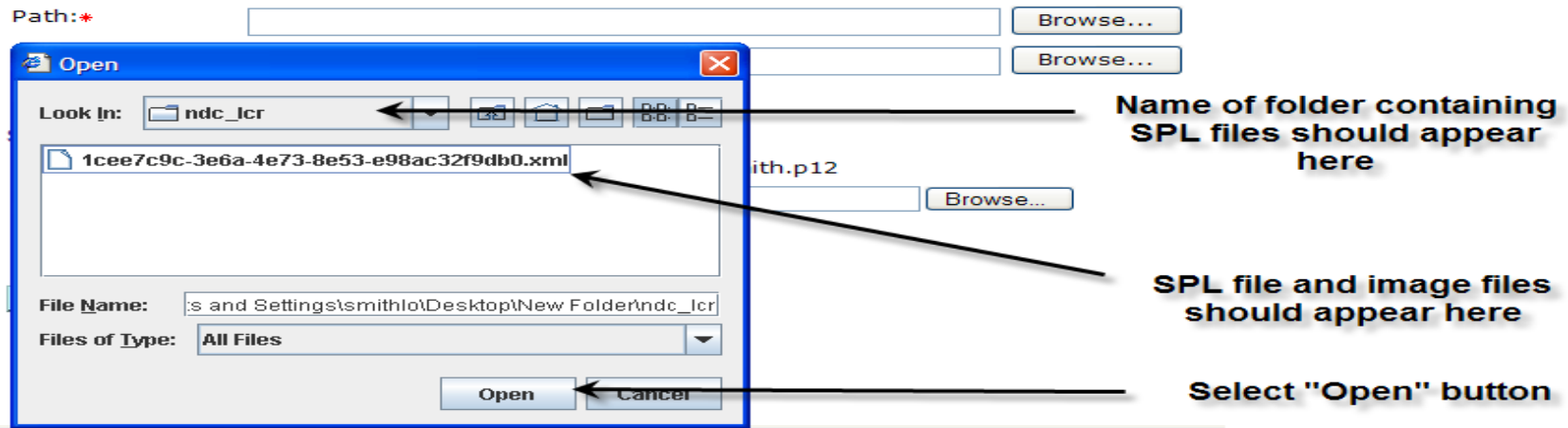
- Select “OC” as the FDA Gateway “center.”
- NDC Labeler Code, Establishment Registration, & Content of Labeling/Listing SPL documents submitted for the purpose of registering a drug establishment and listing a drug product should be sent via “OC.”

# Navigate to Folder w/SPL



- Click browse button to navigate to location of folder containing SPL file (and, if applicable, associated image files.)

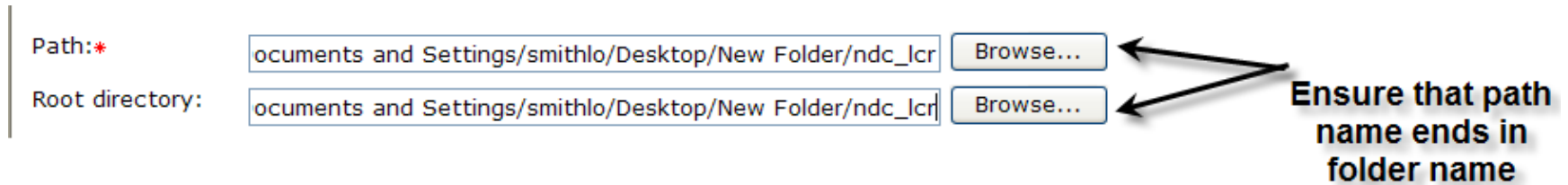
# Selecting SPL Submission



- Ensure that you are sending folder.
- Check to be sure that you are not sending a folder within a folder
- Select "Open" to continue.



# Checking Path Name



- Ensure that path name ends in the name of folder which contains the SPL document and JPEG files.
- If path ends in file name, then you are only sending the file and not the folder containing files.

# Selecting Submission Type

Submission type: \*   ← **Select submission type "SPL"**

- Use drop-down menu to select submission type “SPL.”
- If submission type “SPL” does not appear, you have chosen the wrong center and not “OC.”

# Verify or Select Digital Certificate



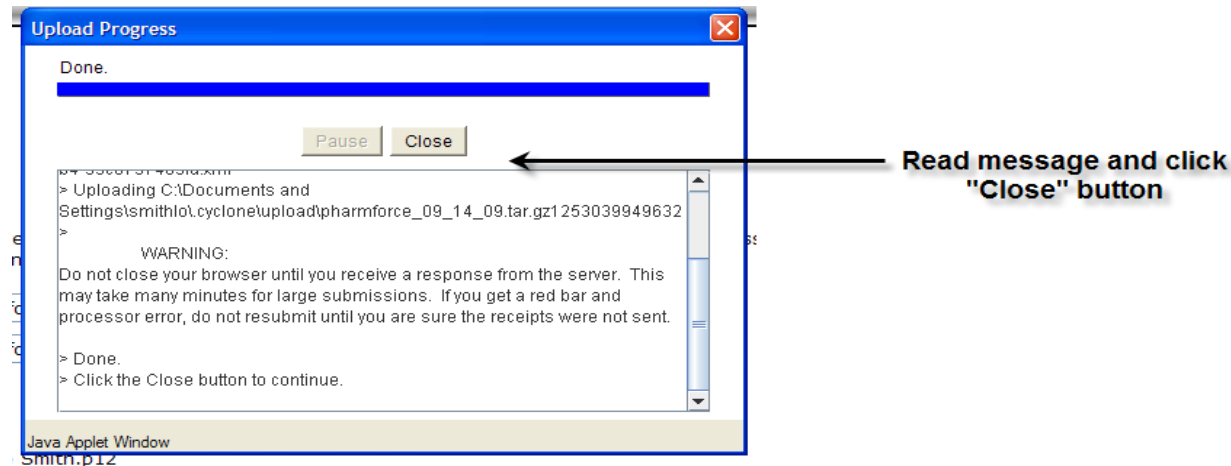
- Verify that your digital certificate is being used.
- Or browse to the location of the digital certificate on your computer.

# Sending the Submission



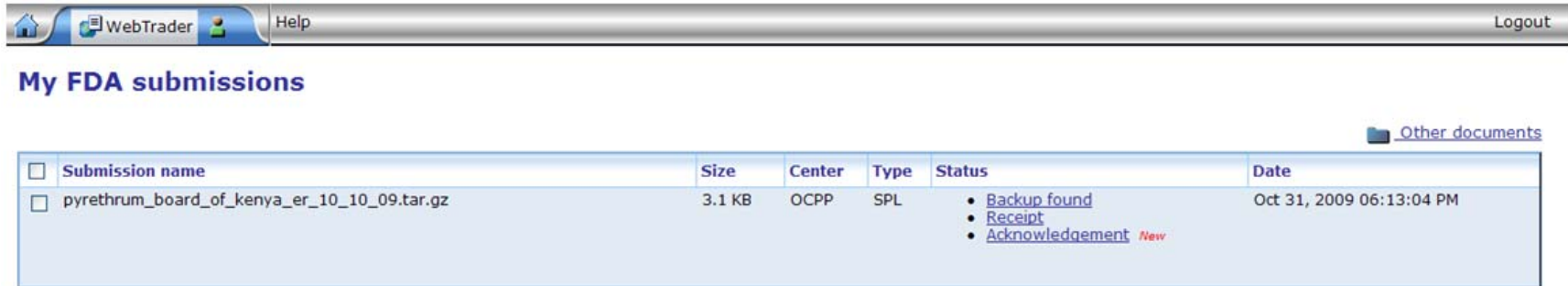
- Select the “Send” button.
- Enter your password to unlock signing certificate.
- Select the “OK” button

# Completing Gateway Submission



- Read message in prompt window
- Select "Close" button

# Log onto FDA Gateway




The screenshot shows the FDA Gateway WebTrader interface. At the top is a navigation bar with a home icon, 'WebTrader' text, a user icon, 'Help', and a 'Logout' link. Below this is a section titled 'My FDA submissions'. To the right of this section is a link for 'Other documents'. The main content is a table with columns: Submission name, Size, Center, Type, Status, and Date. One submission is listed: 'pyrethrum\_board\_of\_kenya\_er\_10\_10\_09.tar.gz' with a size of 3.1 KB, center OCPP, and type SPL. The status column contains a bulleted list of links: 'Backup found', 'Receipt', and 'Acknowledgement' (marked as 'New'). The date is 'Oct 31, 2009 06:13:04 PM'.

<input type="checkbox"/>	Submission name	Size	Center	Type	Status	Date
<input type="checkbox"/>	pyrethrum_board_of_kenya_er_10_10_09.tar.gz	3.1 KB	OCPP	SPL	<ul style="list-style-type: none"><li>• <a href="#">Backup found</a></li><li>• <a href="#">Receipt</a></li><li>• <a href="#">Acknowledgement</a> <i>New</i></li></ul>	Oct 31, 2009 06:13:04 PM

- Log onto the FDA Gateway
- Select the “My FDA submissions” or “Other documents” hyperlinks

# Selecting the File w/Core ID

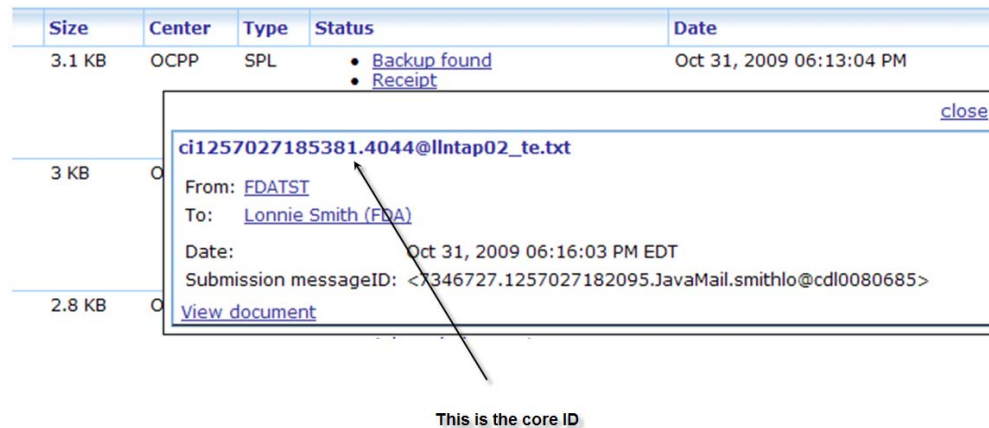
Center	Type	Status	Date
OCPP	SPL	<ul style="list-style-type: none"><li>• <a href="#">Backup found</a></li><li>• <a href="#">Receipt</a></li><li>• <a href="#">Acknowledgement</a> <i>New</i></li></ul>	Oct 31, 2009 06:13:04 PM



Click the "Acknowledgment" hyperlink

- The **first** "Acknowledgment" link should take you to window with core ID.


# Finding the Core ID



- After selecting the “Acknowledgment” hyperlink, window should display.
- Core ID is located in top left of “Acknowledgment” window. (.txt is not part of the actual core ID)
- Use this core ID to reference submission when communicating with FDA about status or issue with SPL document.



# Finding Error Messages



The screenshot shows the FDA Gateway WebTrader interface. At the top is a navigation bar with a home icon, 'WebTrader', a user icon, 'Help', and a 'Logout' link. Below the bar, the heading 'My FDA submissions' is displayed. To the right of this heading is a link for 'Other documents'. Below these elements is a table with columns for Submission name, Size, Center, Type, Status, and Date. A single submission is listed: 'wellness\_center.tar.gz' (3 KB, OCPP, SPL). The Status column for this submission contains a bulleted list of links: 'Backup found', 'Receipt', 'Acknowledgement' (marked as 'New'), and another 'Acknowledgement' link.

<input type="checkbox"/>	Submission name	Size	Center	Type	Status	Date
<input type="checkbox"/>	wellness_center.tar.gz	3 KB	OCPP	SPL	<ul style="list-style-type: none"><li>• <a href="#">Backup found</a></li><li>• <a href="#">Receipt</a></li><li>• <a href="#">Acknowledgement</a> <i>New</i></li><li>• <a href="#">Acknowledgement</a></li></ul>	Oct 31, 2009 03:09:46 PM

- Logon to the FDA Gateway
- Select the “My FDA submissions” or “Other Documents” hyperlinks

# Selecting Error Message

Size	Center	Type	Status	Date
3 KB	OCPP	SPL	<ul style="list-style-type: none"><li>• <a href="#">Backup found</a></li><li>• <a href="#">Receipt</a></li><li>• <a href="#">Acknowledgement</a></li><li>• <a href="#">Acknowledgement</a> <span>New</span></li></ul>	Oct 31, 2009 03:09:46 PM



Click on second (or third) "Acknowledgment" hyperlink

- Receipt of a second or third “Acknowledgment” hyperlink is indicative that there is an error with your submission.
- Click on second (and third, if available) “Acknowledgment” hyperlink.

# Opening Error Messages

The screenshot shows a web interface with a table of messages and a detailed view of a selected message.

Size	Center	Type	Status	Date
3 KB	OCP	SPL	<ul style="list-style-type: none"><li><a href="#">Backup found</a></li><li><a href="#">Receipt</a></li><li><a href="#">Acknowledgement</a> <i>New</i></li></ul>	Oct 31, 2009 03:09:46 PM

[close](#)

ci1257016187076.9279@lntap01\_te.xml

2.8 KB O

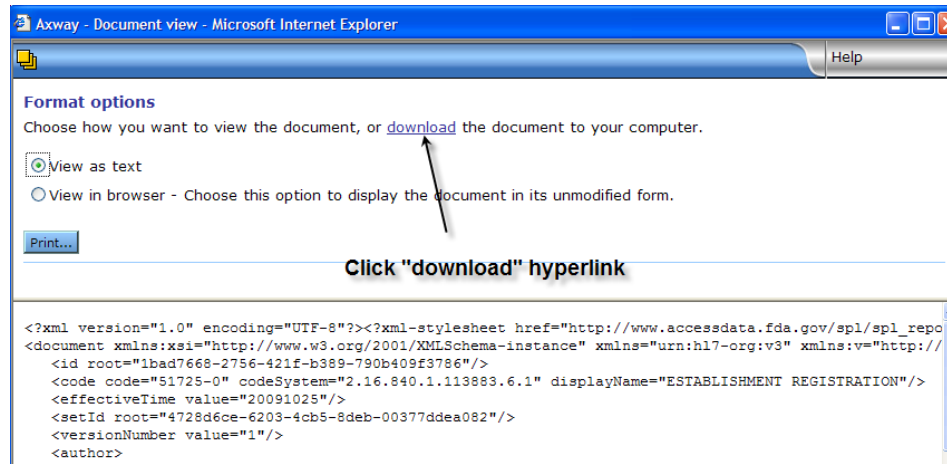
From: [FDATST](#)  
To: [Lonnie Smith \(FDA\)](#)  
Date: Nov 1, 2009 12:34:11 PM EST  
Submission messageID: <18012736.1257016184535.JavaMail.smithlo@cdl0080685>  
[View document](#)

2.7 KB O

Click "View document" hyperlink

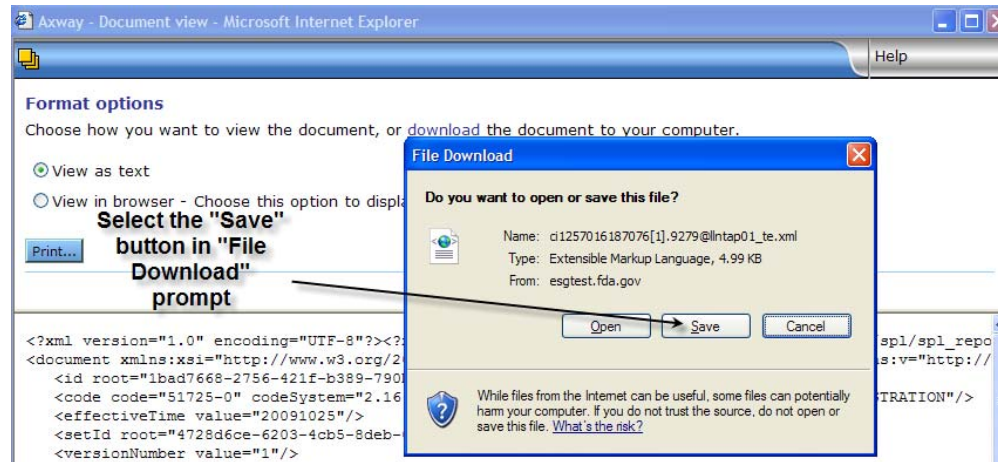
- Click the “View Document” located in the bottom left corner of Acknowledgment prompt window.

# Downloading Error Message



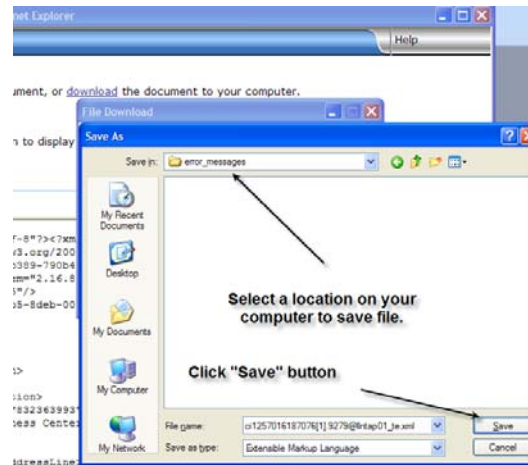
- Select the “download” hyperlink to download the error message to location on computer

# Saving the Error Message Document



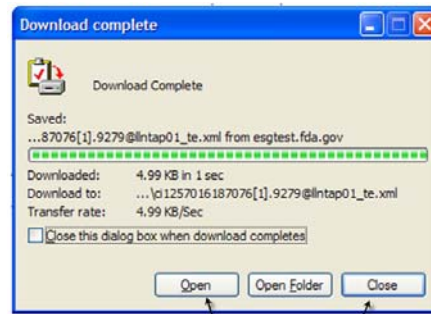
- Click the “Save” button in the “File Download” window prompt.

# Saving the Error Message Document cont...



- Navigate to preferred location on your computer in which to store the error message.
- Click the “Save” button to save message in preferred location.

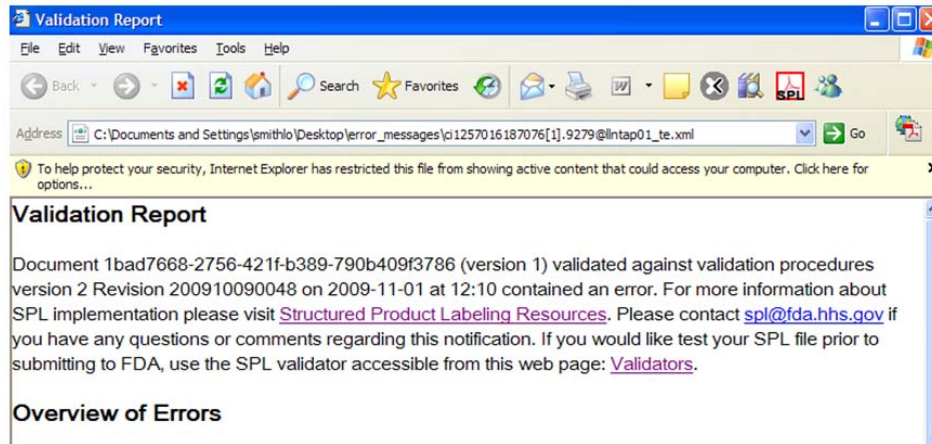
# Completing Download



Select "Open" or "Close" buttons

- You can open the message from the “Download complete” window prompt
- You can also close the window and directly open from location on your computer where message was stored.

# Review the Error Message



- Review the error message



# Configuring PC to View Error Message

- If you are experiencing technical difficulties resulting in your inability to view the error message you have downloaded, we recommend that you follow these steps for Internet Explorer
  - Click the "Tools" menu and select "Internet Options".
  - Click the "Security" tab.
  - Click the "Custom level" button.
  - Scroll down to the "Miscellaneous" section.
  - Enable the "Access data sources across domains".
  - Click "OK" to accept the update.
  - Click "OK" to close the security dialog.

# Test Your SPL R4 Submissions

- Use Pragmatic Data Validator Lite to test your SPL files prior to transmission to FDA:  
<http://www.fda.gov/ForIndustry/DataStandards/ucm155514.htm>
- NOTE
  - This validator tool is **NOT** connected to FDA database.
  - This tool assist you in detection of **90 – 95%** of technical errors in SPL documents.

# Stay Informed

- Join FDA Data Standards Council listserv
- <http://www.fda.gov/ForIndustry/DataStandards/default.htm>



The screenshot shows the FDA Data Standards Council website. At the top is the U.S. Department of Health & Human Services header with the www.hhs.gov URL. Below this is the FDA U.S. Food and Drug Administration logo and a search bar. A navigation bar lists various FDA categories: Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. The 'For Industry' section is highlighted, with a breadcrumb trail: Home > For Industry > Data Standards. On the left is a 'Data Standards' sidebar menu with links to Validators, Data Council, Structured Product Labeling, Individual Case Safety Reports, and Regulated Product Submission. The main content area is titled 'FDA Resources for Standards' and features a sign-up link for email updates, a paragraph describing the council's role, and a link to 'Structured Product Labeling'.

U.S. Department of Health & Human Services www.hhs.gov

**FDA** U.S. Food and Drug Administration

A-Z Index Search  go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

**For Industry** Email this page Print this page Change Font Size

Home > For Industry > Data Standards

**Data Standards**

- Validators
- Data Council
- Structured Product Labeling
- Individual Case Safety Reports
- Regulated Product Submission

**FDA Resources for Standards**

 Sign up for email updates. ←

The FDA Data Standards Council coordinates the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency.

[Structured Product Labeling](#)

# SPL-related Technical Assistance/Questions

- SPL e-mail account ([spl@fda.hhs.gov](mailto:spl@fda.hhs.gov))